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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,283	01/21/2004	Takayuki Asahara	US-106	8761

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EXAMINER	
LILLING, HERBERT J	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/760,283	ASAHARA ET AL.	
	Examiner	Art Unit	
	HERBERT J. LILLING	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) *5-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *5-7* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *(6/10;12-21;12-22;*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Receipt is acknowledged of the election response filed July 20, 2006.

2. Claims 1-7 are pending in this application.

3. Applicant has elected with traverse Group I invention, Claims 1-4. Claims 5-7 have been withdrawn from further consideration Pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 20, 2006.

The restriction is proper as stated since the additional invention would involve an extremely burdensome search and examination for the broad claimed product invention. Applicant had an opportunity to elect the product claim(s) which would have required this examiner to search the process claims upon the allowance of any product in accordance with In re Ochai et al as indicated in paragraph 8 of the last office action mailed June 22, 2006. The search and examination for the additional product claim would involve different classes as well as different computerized bank strategies that would be extremely burdensome for this examiner to meet the goals of this Tech Center and the U.S. Patent Office to reduce pendency.

Thus, the arguments have been deemed not to be persuasive to withdraw the restriction requirement.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Best Mode:

Claims 1-4 rejected under 35 U.S.C. 112, first paragraph, because the best mode contemplated by the inventor can not be employed due to the lack of availability of the best microorganism strain(s) as indicated in the specification by the following:

> "Specific examples of Methylophilus bacterium having an ability to produce L-lysine obtained as described above include, but are not limited to, Methylophilus methylotrophus AJ13608. This strain was bred by imparting the AEC resistance to the Methylophilus methylotrophus AS1 strain. The Methylophilus methylotrophus AJ13608 was deposited at the National Institute of Bioscience and Human-Technology, Agency of Industrial Science and Technology (currently, National Institute of Advanced Industrial Science and Technology, International Patent Organism Depositary, Tsukuba Central 6, 1-1, Higashi 1-Chome, Tsukuba-shi, Ibaraki-ken, 305-8566, Japan) on Jun. 10, 1999 and received an accession number of FERM P-17416. Then, the deposit was converted to an international deposit under the provisions of the Budapest Treaty on Mar. 31, 2000 and received an accession number of FERM BP-7112.
> ---
>
> The E. coli JM109 strain transformed with pRSlysE24 was designated as AJ13830, and this strain was deposited at the independent administrative corporation, National Institute of Advanced Industrial Science and Technology, International Patent Organism Depositary on Jun. 4, 2001 and received an accession number of FERM P-18369. Then the deposit was converted to an international deposit under the provisions of the Budapest Treaty on May 13, 2002 and received an accession number of FERM BP-8040.
> ------
>
> The E. coli JM109 strain transformed with the pRSdapA plasmid was designated as AJ13831, and this strain was deposited at the

independent administrative corporation, National Institute of Advanced Industrial Science and Technology, International Patent Organism Depositary on Jun. 4, 2001 and received an accession number of FERM P-18370. Then, the deposit was converted to an international deposit under the provisions of the Budapest Treaty on May 13, 2002, and received an accession number of FERM BP-8041."

B. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention with respect to the availability as follows:

U.S. Patent Rules of Deposits

It is apparent that the strain(s) is/(are) required to practice the claimed invention(s) as recited in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of strain(s). See 37 C. F. R. 1.802.

The specification does not provide a repeatable method for obtaining the strain(s) and it does not appear to be a readily available material. Deposit of strain(s) would satisfy the enablement requirements of 35 U.S.C. 112. If a deposit has been made, Applicant is required to meet the necessary criteria of the deposit rules in accordance with 37 CFR 1.801-37 CFR 1.809.

If a deposit has not been supplied or made under the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty **and that all restrictions** imposed by the depositor on the availability to the public of the deposited material will be **irrevocably removed** upon the granting of a patent, would satisfy the deposit requirements, See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

b) all restrictions imposed by the depositor on the availability to the public of the deposited material **will be irrevocably** removed upon the granting of a patent;

c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

d) a viability statement in accordance with the provisions of 37 CFR 1.807;

and

e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function n the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification, See 37 CFR 1.803-37 CFR 1.809 for additional explanations of these requirements.

Please note that the mere reference to a deposit or the biological material itself in any document or publication does not necessarily mean that the deposited biological material is readily available. Even a deposit made under the Budapest Treaty and referenced in a United States or foreign patent document would not necessarily meet the test for known and readily available unless the deposit was made under conditions that are consistent with those specified in these rules, including the provision that requires, **with one possible exception (37 CFR 1.808(b)), that all restrictions on the accessibility be irrevocably removed by the applicant upon the granting of the patent. Ex parte Hildebrand, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990).**

Applicant can overcome (B) paragraph rejection upon receipt from the Applicant or Attorney of record, a one-sentence statement:
----- All restrictions imposed by the depositor on the availability to the public of the deposited material(s) [which includes the following strains-please state]- **will be irrevocably** removed upon the granting of a patent."

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) The invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> .(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gunji et al,, US 20030124687 July 03, 2003.
" Method for producing L-lysine or L-arginine by using methanol assimilating bacterium"

> A DNA encoding a variant of a protein, having a loop region and six hydrophobic helixes and involved in excretion of L-lysine to outside of a cell, wherein the DNA encodes a mutant protein not containing the loop region that is contained in a wild-type protein and facilitates excretion of L-lysine, L-arginine or both of these L-amino acids to outside of a cell of a methanol assimilating bacterium when the DNA is introduced into the bacterium, specifically lysE24, is introduced into a methanol assimilating bacterium such as Methylophilus bacteria to improve L-amino acid productivity, especially L-lysine and-L-arginine-productivities.
>
> Examples of Methylophilus methylotrophus include, but are not limited to

> the AS1 strain (NCIMB10515) and so forth. The Methylophilus methylotrophus AS1 strain (NCIMB10515) is available from the National Collections of Industrial and Marine Bacteria (Address: NCIMB Lts., Torry Research Station, 135, Abbey Road, Aberdeen AB9 8DG, United Kingdom).

Claims 1-3 rejected under 35 U.S.C. 102(e) as anticipated by Hanson et al, U.S 6,261,825 July 17, 2001 effective date March 20, 1991; " Production of amino acids using auxotrophic mutants of methylotrophic bacillus".

The reference to Hanson et al discloses the following which anticipates the claimed invention absent a showing that the claimed language contains unexpected or unobvious process steps which includes the requirement of requiring having L-methonine for its growth which is considered to be inherent in the specific strain:

> "Employing auxotrophs and/or amino acid resistant mutants of the type I methylotrophic bacterium of the present invention it is believed that amino acids can be produced in substantial quantities..... While the present invention is believed useful to produce many of the 20 amino acids, it is especially useful **to produce lysine**, ... In one embodiment, auxotrophs which are also amino acid sensitive can produce from about 3 to about 5 g.multidot.l.sup.-1 of lysine. In a preferred embodiment, auxotrophs which are also amino acid sensitive can produce up to 8 grams/l L-lysine.
> ---
> A culture of Methylophilus methylotrophus grown in MV medium at 37.degree. C. and a culture of strain MGA3 grown in MV at 50.degree. C. and then switched to 37.degree. C. were each the source of 70 mg (wet weight) of cell paste."

6. **No claim is allowed.**

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is 571-272-0918** and **Fax Number** is (703) 872-9306 or SPE Michael Wityshyn whose telephone number is 571-272-0926. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://portal.uspto.gov/external/portal/pair**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit **1651**
August 03, 2006

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Group 1600 Art Unit 1651